

Remarks

Claims 1-20 are pending. Claims 1-12 have been withdrawn from consideration and claims 13 to 20 stand rejected by the final Office action dated January 18, 2007. Applicants filed an amendment after final rejection on March 19, 2007 (delivered electronically; March 18, 2007 being a Sunday) that included an affidavit under Rule 132. An Advisory Action issued on April 4, 2007 (delivered electronically) which stated that, for purposes of appeal, claims 13-20 are rejected, the amendment after final would be entered but the affidavit would not be entered because applicant failed to provide good and sufficient reasons why the affidavit is necessary and was not earlier presented (37 C.F.R. 1.116(e)). The Advisory Action also provided additional remarks related to the rejections made earlier under §§ 102 and 103. Applicants filed on April 16, 2007 (by facsimile) a Notice of Appeal with authorization to charge the fee due in connection with that filing. This amendment, filed with a request to withdraw finality or, alternatively with the Request for Continued Examination (RCE), amends claim 16. In either case, Applicants request entry and consideration of the Amendment and Declaration filed on March 19, 2007 in further examination of this application.

Applicants have filed a Request for Continued Examination that accompanies this Amendment, which is considered a submission under 37 CFR 1.114(c). The RCE form (PTO/SB/30EFS) requests that the previously filed amendment after final rejection and its accompanying affidavit (Declaration of Steven T. Brentano Under Rule 132) be entered, and authorizes the Director to charge the RCE fee under 37 CFR 1.17(e) to the Deposit Account maintained in the name of Gen-Probe Incorporated. If any additional fee is due in connection with filing the RCE and this Amendment, authorization is provided herein for the Director to charge all required fees to the same Deposit Account.

To avoid duplication of information contained in already filed documents, Applicants respectfully request that the Examiner refer to the Amendment and Declaration filed March 19, 2007, for which the contents of both are incorporated by reference herein. If the Office requires re-transmission of the Declaration of Steven T. Brentano Under Rule 132 (filed March 19,

2007), Applicants request that the Examiner contact Applicants' representative to request the re-transmission before examination of the application continues.

The Advisory Action stated that the proposed amendments did not place the application in condition for allowance for reasons described in the Advisory Action continuation sheet. The following comments respond.

With regard to the rejection of claim 16 under § 102, Applicants thank the Examiner for the comments in the Advisory Action that clarify the interpretation of claim 16 "drawn using open claim language" (see Office action dated 01/18/2007 at page 3, lines 2-3). Applicants appreciate the acknowledgment that the plain meaning of the term "kit" is reasonably a group of things (oligonucleotides), which presumably excludes alternative definitions provided in the Advisory Action that are inconsistent with the disclosure of the present application (e.g., "a group of persons"). Applicants maintain that a person of ordinary skill in the art of molecular biology would reasonably interpret the claim language to mean that oligonucleotides in a kit, specified by SEQ ID numbers, are molecular compounds that would require some container to hold the compounds. Applicants appreciate the Examiner's suggestion of language that would overcome the § 102 rejection, which has been used in amending claim 16. Accordingly, Applicants request allowance of claim 16.

With regard to the § 103 rejections, the Advisory Action stated that "Buck et al. is an example of the state of the art at the time the invention was made. Further, Hogan et al. ... [cited earlier] discussed selecting primers to target regions that would not have hinderences [sic] to amplification. These together show that this was routine practice." The Advisory Action further states that "The Buck reference is cited to demonstrate that primers selected from throughout a nucleotide sequence would be capable of PRIMING and [sic] extension reaction, and thus, absent a secondary consideration the selection of any and all oligonucleotides for priming the sequence taught by the Gen-Bank record would have been obvious."

Applicants first note that the Advisory Action paraphrases statements that appear to be somewhat inconsistent with those made in the rejections under § 103 made in the Office action dated 07/28/2006, and maintained in Office action dated 1/18/2007. With regard to Hogan et al., the Advisory Action relies on Hogan et al. for "selecting primers" to target regions that would not have hindrances to amplification. In contrast, the §103 rejection that relied on Hogan et al. (Office action dated 07/28/2006, pages 6-7) stated that "Hogan et al. teach compositions comprising oligonucleotide probes that target the 16S rRNA region of Mycobacterium species (Col. 2, lines 40-45, for example)." (Underline added herein.) The Office action (page 7) also quotes Hogan et al. (citing Col 6, line 48-Col. 7, line 13) in a section that contains the following statements (underlines added herein):

.... At this point, the sequences are examined to identify potential target regions. Two important objectives in designing a probe are to maximize homology to the target sequence(s) ... and to minimize homology to non-target sequence(s).... We have identified the following useful guidelines for designing probes with the desired characteristics.

First, probes should be positioned so as to minimize the stability of the probe:nontarget nucleic acid hybrid. Second, the stability of the probe:target nucleic acid hybrid should be maximized. Finally, probes with extensive self complementarity should be avoided.

Applicants respectfully note that Hogan et al. describe "probe" oligonucleotides and do not describe primers, amplification, or hindrances to amplification.

With regard to Buck et al., the Advisory Action states that "[t]he Buck reference is cited to demonstrate that primers selected from throughout a nucleotide sequence would be capable of PRIMING [an] extension reaction" The Office action dated 07/28/2006 relied on Buck et al. (see pages 10-11) to "provide evidence of the equivalence of primers" which Applicants submit is broader and is supported by the emphatic conclusions stated about Buck et al. in the Office action. For example, page 11 of the Office action (all emphasis provided in the Office action) included the following statements:

When Buck tested each of the primers selected by the methods of the different labs, Buck found that EVERY SINGLE PRIMER worked (see page 533, column 1). Further, EVERY SINGLE CONTROL PRIMER functioned as well (see page 533, column 1). Buck expressly states 'The results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely high quality (page 535, column 2).' This clearly shows that every primer would have a reasonable expectation of success.

In the Amendment filed October 30, 2006, Applicants representative presented arguments (pages 14-16) that responded to the alleged "evidence of the equivalence of primers" based on information in the Buck et al. reference. The final Office action dated 01/18/2007 (page 7) noted Applicants arguments in support of the conclusion "that Buck et al. do not demonstrate the equivalence of primers." But the paragraph concluded that "Arguments of counsel are not found to be persuasive in the absence of a factual showing." The Office action further provided the following quotation (see page 8):

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant."

The § 103 rejection was maintained (made final), with the comment that Applicants' position that all primers to a known sequence would not all function as equivalents would be better received in view of an evidentiary showing.

Based on the statements in the final Office action that rejected arguments of counsel about the cited Buck et al. reference based on information in that reference, and the invitation to provide an evidentiary showing to support the position that all primers to a known sequence

would not all function as equivalents, Applicants provided the Declaration of Steven T. Brentano with the response filed March 19, 2007. The declaration discussed the Buck et al. reference and provided evidence that all primers do not function equivalently. Thus, Applicants submit that the declaration provides evidence and arguments about the inoperability of the cited prior art for the broad conclusion for which it was cited, i.e., the alleged "equivalence of primers." The Advisory Action stated that the declaration would not be entered because Applicants failed to provide a showing of good and sufficient reasons why the affidavit is necessary and not earlier presented. Applicants respectfully traverse on the grounds that the declaration was made necessary by the comments presented in the final Office action which rejected arguments of counsel (based on teachings in the cited reference) and invited an evidentiary showing for the position that all primers to a known sequence would not function equivalently. That is, an affidavit about the inoperability of the cited prior art for the alleged equivalence of primers was only required after the Office had rejected the arguments of counsel based on information contained in the cited reference.

Conclusion

Based on the above comments, Applicants respectfully request withdrawal of the finality of Office action dated 01/18/2007, entry of the Amendment filed March 19, 2007 and the accompanying Declaration, also filed March 19, 2007, and continued examination on the merits. If withdrawal of finality is not granted, Applicants request continued examination based on the accompanying RCE form and payment of fee, with entry of the Amendment filed March 19, 2007, the Declaration filed March 19, 2007, and the amendment to claim 16 presented herein.

The undersigned has made a good-faith effort to address all the points raised in the final Office action and the Advisory Action and to place the claims in condition for allowance. If matters remain that could be resolved by telephone interview before an Office action is issued, the Examiner is invited to contact the undersigned at the telephone number shown below.

Application Serial No. 10/665,708
Filed: September 18, 2003
AMENDMENT ACCOMPANYING RCE

Confirmation No. 6892
Atty. Docket No. GP107-03.DV1

Authorization to Charge All Required Fees

No fee is believed due in connection with this Amendment that accompanies the RCE. Authorization is hereby provided to debit all required fees, including the RCE fee and any additional required fees, from Deposit Account No. 07-0835 maintained in the name of Gen-Probe Incorporated.

Respectfully Submitted,

Dated: June 7, 2007

By: Christine A. Gritzmacher
Christine A. Gritzmacher
Attorney of Record, Reg. No. 40,627

GEN-PROBE INCORPORATED
Patent Department
10210 Genetic Center Drive
San Diego, CA 92121
Tel.: (858) 410-8926, FAX: (858) 410-8928